REMARKS

By these amendments, claims 12, 19, and 20 are amended and new claims 53-56 are added. Reconsideration and allowance in view of the foregoing amendments and the following remarks are respectfully requested.

DISAVOWAL OF PREVIOUS REMARKS

Applicants hereby disavow any and all previous remarks made during the prosecution of this application. In considering the scope of the prior art, the present claims, and any and all claim recitations within the claims, only the following remarks, in combination with the originally filed application itself should be considered.

PRESUMABLY ALLOWABLE SUBJECT MATTER

Applicants initially note that claims 7 and 21 are listed as rejected on the cover sheet of the Office Action, but the Office Action contains no substantive rejection of them. If the Examiner agrees that these claims are patentable and/or contain allowable subject matter, Applicants request that the next Official Communication state this. Otherwise, Applicants ask the Examiner to issue a new non-final Office Action. *See* MPEP § 706.07(a) ("[S]econd or any subsequent actions on the merits shall be final, except where the examiner introduces a new ground of rejection that is neither necessitated by applicant's amendment of the claims nor based on information submitted in an information disclosure statement filed during the period set forth in 37 CFR 1.97(c) with the fee set forth in 37 CFR 1.17(p).").

ANTICIPATION REJECTION OVER GORDON

Claims 1, 3, 4, 8, 12, 19, 20, 39-41, 44, 47, and 48 were rejected under 35 U.S.C. § 102(b) as anticipated by Gordon (U.S. Patent No. 4,617,557). Applicants respectfully traverse this rejection for the following reasons.

Claim 1

Applicants traverse this rejection of claim 1 for several reasons.

First, claim 1 recites, among other things, "at least one container containing a drug for delivery to a patient in a drug delivery device." While the Office Action alleges that Gordon discloses "at least one container containing a drug," the Office Action fails to allege, must less demonstrate that Gordon discloses that the drug is "for delivery to a patient in a drug delivery

device," as recited in claim 1. 5/30/08 Office Action, p. 2. Indeed, the drug disclosed in Gordon comprises "tablets" or "capsules" capable of being dispensed via a "blister packages." *See* Gordon, col. 1, line 47. Patients take such "tablets" and "capsules" by hand, rather than by "delivery to a patient in a drug delivery device," as recited in claim 1.

To the extent that the Office Action ambiguously asserts that Gordon's blister package comprises a "drug delivery device," Applicants specifically traverse such an assertion. A blister package is merely a container for a drug/medication. A blister package is not a "drug delivery device" because it is not used to actually *deliver* the drug to the patient. The present application discloses a variety of non-limiting, exemplary "drug delivery device[s]." *See, e.g.,* the present application, p. 1, line 6, to p. 2, line 54.

Moreover, it would not have been obvious to adapt Gordon's device to a "drug for delivery to a patient in a drug delivery device," because Gordon is entirely focused on blister packages. *See* Gordon, col. 2, lines 10-25 ("The present invention discloses a method and apparatus … particularly suitable for use with individual dosage packaging, such as blister packs.").

Second, claim 1 recites, among other things, that "the electronic data carrier further includes a radio frequency device for transmitting the drug treatment information to the drug delivery device." While the Office Action alleges that Gordon discloses "the data carrier is arranged to be powered inductively from a radio frequency signal," the Office Action fails to allege, must less demonstrate that Gordon discloses that "the electronic data carrier further includes a radio frequency device for transmitting the drug treatment information to the drug delivery device," as recited in claim 1. 5/30/08 Office Action, p. 2. Indeed, the Office Action does not identify any "drug delivery device" whatsoever in Gordon. In fact, Gordon does not disclose or suggest such a drug delivery device, much less the recited "radio frequency device for transmitting the drug treatment information to" such a "drug delivery device."

Moreover, to the extent that the Office Action ambiguously asserts that Gordon's blister package comprises a "drug delivery device" (Applicants dispute this as explained above), Gordon fails to disclose the transmission of drug treatment information from the asserted electronic data carrier (i.e., housing 64) to the asserted drug delivery device (i.e., the blister

package), as Gordon teaches only the one-way communication from the blister package (see Gordon, FIG. 6) to the asserted electronic data carrier (i.e., housing 64) (see Gordon, FIG. 5). Thus, Gordon fails to disclose a combination including, among other recitations, that "the electronic data carrier further includes a radio frequency device for transmitting the drug treatment information to the drug delivery device."

For at least these reasons, Applicants respectfully request the withdrawal of this anticipation rejection of claim 1, as well as its dependent claims, which are patentable at least because they depend from a patentable independent claim.

New claim 53 further distinguishes one or more embodiments of the present invention from Gordon by reciting that "the drug is configured for delivery to the patient via nebulization of the drug and inhalation of the nebulized drug by the patient." In contrast, as explained above, Gordon discloses the use of drugs in the form of manually ingested tablets/capsules, rather than a drug that "is configured for delivery to the patient via nebulization of the drug and inhalation of the nebulized drug by the patient," as recited in claim 53.

Claims 3 and 12

Applicants also specifically traverse this rejection as applied to dependent claims 3,

Dependent claim 3 recites, among other things, that "the drug is adapted for delivery in air inhaled by the patient to their lungs." The Office Action does not even allege that Gordon discloses such a combination of recitations, much less point to any specific part of Gordon as disclosing such. Indeed, because Gordon is directed solely to manually swallowed tablets/capsules, rather than drugs delivered via a drug delivery device, Gordon does not disclose or otherwise render obvious that "the drug is adapted for delivery in air inhaled by the patient to their lungs," as recited in claim 3. Applicants therefore respectfully request the withdrawal of this anticipation rejection of claim 3 for this additional reason.

Dependent claim 12 recites, among other things, that "the memory is configured to store information received from the drug delivery device." The Office Action does not even allege that Gordon discloses such a combination or recitations, much less point to any specific part of Gordon as disclosing such. Indeed, because Gordon is directed solely to manually swallowed tablets/capsules, rather than drugs delivered via a drug delivery device, Gordon does not disclose

or otherwise render obvious that "the memory is configured to store information received from the drug delivery device," as recited in claim 12. Applicants therefore respectfully request the withdrawal of this anticipation rejection of claim 12 for this additional reason.

Claim 19

Applicants traverse this rejection of claim 19 for several reasons.

First, claim 19 recites, among other things, "a drug delivery device." The Office Action has not even alleged that Gordon discloses a "drug delivery device." *See* 5/30/08 Office Action, p. 2. Indeed, as explained above, Gordon does not disclose or suggest a "drug delivery device," because Gordon is exclusively directed toward manually swallowed tablets/capsules, rather than drugs that are delivered via a "drug delivery device," as recited in claim 19.

Second, claim 19 recites, among other things, "an electronic data carrier for use with the drug delivery device and removable from the drug delivery device," and "an output for transmitting the treatment information via a radio frequency signal from the memory to the drug delivery device." Because, as explained above, Gordon discloses no "drug delivery device," Gordon also fails to disclose the recited relationships between the missing drug delivery device and the recited electronic data carrier or output.

Moreover, to the extent that the Office Action ambiguously asserts that Gordon's blister package comprises a "drug delivery device" (Applicants dispute this as explained above), Gordon fails to disclose or suggest "an output for transmitting the treatment information via a radio frequency signal from the memory to the drug delivery device," as recited in claim 19. Specifically, Gordon fails to transmit drug treatment information from the asserted electronic data carrier (i.e., housing 64) to the asserted drug delivery device (i.e., the blister package), as Gordon teaches only the one-way communication from the blister package (see Gordon, FIG. 6) to the asserted electronic data carrier (i.e., housing 64) (see Gordon, FIG. 5). Thus, Gordon fails to disclose a combination including, among other recitations, "an output for transmitting the treatment information via a radio frequency signal from the memory to the drug delivery device."

For at least these reasons, Applicants respectfully request the withdrawal of this anticipation rejection of claim 19.

New claim 54 further distinguishes one or more embodiments of the present invention from Gordon by reciting, among other things, that "the drug delivery device comprises an electronic input configured to receive the treatment information from the output via the radio frequency signal." Gordon's ambiguously alleged drug delivery device (i.e., the blister package) includes no such input.

Claim 20

Applicants traverse this rejection of claim 20 for several reasons.

First, claim 20 recites, among other things, "a drug delivery device." As explained above, Gordon does not disclose or suggest a "drug delivery device," as Gordon is exclusively directed toward manually swallowed tablets/capsules, rather than drugs that are delivered via a "drug delivery device," as recited in claim 20.

Second, claim 20 recites, among other things, "an electronic data carrier removable from the drug delivery device," and "a radio frequency input which is configured to receive the treatment information from the electronic data carrier over a radio frequency signal, whereby the drug delivery device is configured to deliver the drug in conformity with the treatment information." The Office Action does not even allege, must less demonstrate, that Gordon discloses such a combination of recitations.

Third, claim 20 recites, among other things, that the drug delivery device has "an electronic input for receiving treatment information relating to the drug." As explained above, Gordon's ambiguously alleged drug delivery device (i.e., the blister package) includes no such electronic input.

For at least these reasons, Applicants respectfully request the withdrawal of this anticipation rejection of claim 20.

New claim 55 further distinguishes one or more embodiments of the present invention from Gordon by reciting that "the drug delivery device comprises a nebulizer." As explained above, Gordon does not disclose or suggest a "nebulizer."

Claims 39, 40, and 47

Applicants traverse this rejection of claims 39, 40, and 47 for several reasons.

First, claims 39, 40, and 47 each recite, among other things, that "each container contain[s] a drug for delivery to a patient in a drug delivery device." While the Office Action alleges that Gordon discloses "at least one container containing a drug," the Office Action fails to allege, must less demonstrate that Gordon discloses that the drug is "for delivery to a patient in a drug delivery device," as recited in claims 39, 40, and 47. 5/30/08 Office Action, p. 2. Indeed, as explained above with respect to claim 1, Gordon does not disclose a "drug for delivery to a patient in a drug delivery device," as recited in claims 39, 40, and 47.

Second, claims 39, 40, and 47 each recite, among other things, that "the carrier include[es] drug treatment information for use by the drug delivery device." Because Gordon discloses no such "drug delivery device," Gordon also fails to disclose that "the carrier include[es] drug treatment information for use by the drug delivery device," as recited in claims 39, 40, and 47.

Third, claims 39, 40, and 47 each recite, among other things, that "the data carrier is arranged to be powered inductively from a radio frequency signal transmitted from or associated with the drug delivery device." Because Gordon discloses no such "drug delivery device," Gordon also fails to disclose that "the data carrier is arranged to be powered inductively from a radio frequency signal transmitted from or associated with" such a missing "drug delivery device," as recited in claims 39, 40, and 47.

Moreover, the Office Action alleges that the "data carrier" in Gordon is the housing 64 shown in FIG. 5 of Gordon. *See* 5/30/08 Office Action, p. 4. Gordon does not disclose or suggest that this housing 64 is "powered inductively," as recited in claims 39, 40, and 47.

For at least these reasons, Applicants respectfully request the withdrawal of this anticipation rejection of claims 39, 40, and 47, as well as their dependent claims, which are allowable at least because they depend from an allowable independent claim.

Applicants traverse this rejection of claim 47 for an additional reason as well. Claim 47 recites, among other things, that "the data carrier is arranged to generate the radio-frequency signal bearing the treatment information." The Office Action's alleged data carrier comprises a housing 64, which transmits no information via a radio frequency signal, much less treatment information. Accordingly, Gordon fails to disclose or suggest that "the data carrier is arranged

to generate the radio-frequency signal bearing the treatment information," as recited in claim 47. Applicants therefore respectfully request the withdrawal of this rejection of claim 47 for this additional reason.

OBVIOUSNESS REJECTION OVER ANDERSON IN VIEW OF GORDON

Claims 13, 16-19, 51, and 52 were rejected under 35 U.S.C. § 103(a) as obvious over Anderson (U.S. Patent No. 5,237,987) in view of Gordon. Applicants respectfully traverse this rejection for the following reasons.

Claim 13

Claim 13 recites, among other things, "a delivery controller for controlling the amount of the drug delivered to the patient based on the received treatment information." While the Office Action asserts that Anderson discloses "a delivery controller," the Office Action fails to even alleged that Anderson's "delivery controller" is "for controlling the amount of the drug delivered to the patient based on the received treatment information," as also recited in claim 13. Indeed, Anderson fails to disclose such a combination of recitations. At most, Anderson discloses that EPROMs are removably connected to Anderson's controller 28 to "control various aspects of the individual subsystems." Anderson, col. 12, line 58, to col. 13, line 3. Anderson does not disclose, suggest, or otherwise render it obvious that such EPROM memories include treatment information, much less treatment information used by the delivery controller "for controlling the amount of the drug delivered to the patient," as recited in claim 13.

The Examiner's proposed modification of Anderson in view of Gordon does not cure this deficiency. Specifically, the Examiner asserts that Gordon would have made it obvious to connect Anderson's EPROM memories to Anderson's controller 28 via a radio frequency signal, rather than Anderson's disclosed physical "insert[ion] [of the EPROM memories] into the microprocessor boards" of the controller 28. Anderson, col. 13, lines 2-3; *see also* 5/30/08 Office Action, p. 5. Even if Anderson's EPROM memories were connected to Anderson's controller 28 via a radio frequency signal, as proposed by the Examiner, the memories still would not include treatment information used by the delivery controller "for controlling the amount of the drug delivered to the patient," as recited in claim 13.

Applicants therefore respectfully request the withdrawal of this obviousness rejection of claim 13, as well as its respective dependent claims, which are allowable at least because they depend from allowable independent claim 13.

Claim 16

Applicants also specifically traverse this rejection of claim 16, which recites, among other things, that "the electronic input is additionally arranged to transmit treatment information to the electronic data carrier for recordal." The Office Action fails to even allege that the Examiner's proposed combination of Anderson in view of Gordon discloses such a combination of recitations. Indeed, the proposed combination does not render this combination of recitations obvious. By their very definition, Anderson's EPROM memories (i.e., "Erasable Programmable Read Only Memories") (Anderson, col. 12, line 68, to col. 12, line 1) provide for one way data communication from the memories to the controller 28. There is no disclosure or suggestion in Anderson to modify such EPROM memories and Anderson's controller 28 such that the controller 28 transmits treatment information to the EPROM memories.

Gordon does not cure this deficiency. The Office Action proposes that Gordon would have made it obvious to have incorporated a radio frequency signal into Anderson's ventilation system, but does not assert that it would have been obvious to make any other modification to Anderson's ventilation system in view of Gordon. Accordingly, by the Office Action's own account, Gordon does not render obvious any other modification to Anderson (e.g., modifying Anderson in view of Gordon such that Anderson's controller 28 transmits treatment information to Anderson's EPROM memories).

Moreover, even if the Office Action did allege that it was obvious to so modify Anderson in view of Gordon, the proposed modification would have been nonobvious. As explained above, Gordon is exclusively focused on patient compliance relating to the administration of capsules/tablets from a blister package. Such compliance and blister packages are irrelevant to Anderson's use of a nebulizer for nebulizing a liquid medicament that is administered by a medical professional. Moreover, Gordon does not disclose two-way communication between an electronic data carrier and an electronic input (e.g., an "electronic input …for receiving treatment information from a removable electronic data carrier" (claim 13), wherein the

"electronic input is additionally arranged to transmit treatment information to the electronic data carrier for recordal"). Thus, Anderson and Gordon, either alone or in combination, fail to render obvious the combination of recitations in claim 16. Applicants therefore respectfully request the withdrawal of this obviousness rejection of claim 16 for this additional reason.

New claim 56 further distinguishes one or more embodiments of the present invention from Gordon and Anderson by reciting, among other things, that "the electronic input is configured to transmit treatment information via a radio frequency signal to the removable electronic data carrier." Anderson's drug delivery device is not so configured. Gordon does not cure this deficiency. Accordingly, Gordon and Anderson, both individually and in combination, fail to disclose or otherwise render obvious such a combination of recitations.

Claim 17

Applicants also specifically traverse this rejection of claim 17, which recites, among other things, that "the drug delivery device includes an authorization portion which prevents delivery if any of the treatment information indicates that the drug is unsuitable for delivery." The Office Action asserts that "col. 12, lines 11-18" of Anderson disclose "an authorization portion." 5/30/08 Office Action, p. 5. To the contrary, the cited passage does not disclose such an authorization portion. Moreover, Anderson includes no disclosure whatsoever regarding the prevention of delivery of a drug if the drug is unsuitable for delivery. Indeed, Anderson includes only a cursory mention of the use of a "nebulizer 48 [to] add medication, such as for example a decongestant, to the gas flow 36." Anderson, col. 6, lines 40-41. Gordon does not cure this deficiency. Applicants therefore respectfully request the withdrawal of this obviousness rejection of claim 17 for this additional reason.

Claim 19

Amended claim 19 recites, among other things, "a memory located within the electronic data carrier for holding drug-specific treatment information concerning the use of the drug delivery device in delivering a specified drug." In contrast, Anderson's EPROM memories include information relating to the operation of Anderson's ventilator, but do not include "drug-specific treatment information concerning the use of the drug delivery device in delivering a specified drug," as recited in amended claim 19. Gordon does not cure this deficiency because,

as explained above, Gordon's blister-package-specific teaching has no obvious bearing on Anderson's ventilation system's use of a nebulizer.

Applicants therefore respectfully request the withdrawal of this obviousness rejection of claim 19, as well as its respective dependent claims, which are allowable at least because they depend from allowable independent claim 19.

CONCLUSION

All objections and rejections have been addressed. It is respectfully submitted that the present application is in condition for allowance and notice to that effect is earnestly solicited.

Should the Examiner believe that anything further is desirable to place the application in better condition for allowance, the Examiner is invited to contact the undersigned at the telephone number listed below.

This response is being filed within three months after the expiration of the three-month shortened statutory period which expired on August 30, 2008. A request for an extension of time has been included. Please charge any fees associated with the submission of this paper to Deposit Account Number 14-1270. The Commissioner for Patents is also authorized to credit any over payments to the above-referenced Deposit Account.

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